

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

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In re: PHARMACEUTICAL INDUSTRY)	MDL No. 1456
AVERAGE WHOLESAL PRICE LITIGATION)	
<hr/>)	Master File No. 01-12257-PBS
)	
)	Subcategory No. 07-11618-PBS
THIS DOCUMENT RELATES TO:)	
)	
<i>United States of America ex rel. Ven-A-Care of the</i>)	Hon Patti B. Saris
<i>Florida Keys, Inc. v. Abbott Laboratories, Inc.,</i>)	
Civil Action No.07-11618-PBS)	
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**VEN-A-CARE OF THE FLORIDA KEYS, INC.’S SURREPLY TO ABBOTT
LABORATORIES REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF
SUBJECT MATTER JURISDICTION UNDER THE FALSE CLAIMS ACT**

A. There was no public disclosure concerning Abbott’s Ery Drugs

As was true for the other reply briefs on the motions to dismiss, Abbott added very little to what it already argued in its initial motion. Once again, it’s the same documents and the same arguments, none of which effectively shows that the fraud by Abbott with respect to its Erythromycin drugs had been publicly disclosed before Plaintiff Ven-A-Care of the Florida Keys, Inc. (hereafter “Ven-A-Care” or “VAC”) filed its complaint on these drugs. Whether viewed separately or collectively, the cited public disclosures fail to identify Abbott or the specific prices for its drugs. Ven-A-Care, in its answering brief, explained why the 1984 report does not suggest fraud or identify EES and noted prices only formulaically lower than AWP, not the higher spreads off of WAC alleged by relator (Response of Relator at pp. 2-5). This Court has previously found that reports showing mere averages are insufficient, *United States ex rel. Ven-A-Care v. Actavis Mid-Lantic, LLC*, 2009 U.S. Dist. LEXIS 92945 (D. Mass. Oct. 2, 2009). Abbott can not undercut that holding by its references to additional reports containing averages.

The best Abbott can muster is an argument that the cognizable public disclosures, if scrutinized by the government with the benefit of information elsewhere in its vast files, provided some pricing information for Abbott drugs. There is admittedly no indication of fraud. Plaintiff incorporates by reference its arguments set forth in Ven-A-Care's Surreply To Reply Briefs of Abbott, Dey, and Roxane in Support of Motions To Dismiss where it has extensively discussed the reasons why these attenuated public disclosure arguments are not sufficient. *See* especially pages pps 4-9.

Curiously, the only new alleged public disclosure that Abbott has cited in its Ery reply brief is a study of reimbursement prices in the *Canadian* health system versus reimbursement prices in the United States. *See* Comparison of Reimbursement Prices for Multiple Source Prescription Drugs in the United States and Canada, OEI-03-91-00470 (Abbott Exh. 25). Admittedly, this report discloses some Erythromycin prices – but with no reference to Abbott and the prices are compared only to prices in Canada (specifically, Ontario, Canada), under very different health, insurance, and procurement systems than exist in the United States. There has been, and could be, no showing by Abbott that prices of drugs in Canada are informative of prices here in the United States. To the contrary, as has been heavily covered in the news and in congressional hearings, there is a widespread perception that drugs are cheaper in Canada, thus leading to extensive lobbying to permit drug reimportation from Canada so as to make those prices accessible here. *See* Declaration of Susan Schneider Thomas Submitting Exhibits Relied Upon in Ven-A-Care of the Florida Keys, Inc.'s Surreply to Abbott Laboratories Reply in Support of Motion to Dismiss for Lack of Subject Matter Jurisdiction Under the False Claims Act (“Thomas Decl.”) Ex. A, *Importing Less Expensive Drugs Not Seen as Cure for U.S. Woes*, www.nytime.com/2004/10/16

HCFA itself (the predecessor agency to CMS) commented in response to this particular study that “comparing U.S. and Canadian drug pricing is not useful because of ‘enormous differences’ between the two systems.” Abbott Exh. 25 at C-3. The differences include the existence of a national health insurance program in Canada, which allows the Canadian government to purchase drugs directly from manufacturers at negotiated prices. Additionally, the Canadian government controls whether a drug may be marketed in Canada, and at what price. *Id.* at C-3. Other criticisms of the comparisons pointed out that there are different prescribing patterns in the United States and Canada, leading to different demand patterns, and that a government-set price takes awhile, so currency exchange differences may lag. *Id.* at C-6.

It is quite puzzling what significance Abbott believes it can demonstrate from this report about drug reimbursement prices in Canada. Obviously there would be no allegations of AWP fraud because the Canadian insurance system does not pay or reimburse for drugs on that basis. *See* Abbott Exh. 25 at 2 (“In the Canadian province of Ontario, payments for prescription drugs are based on the best available price (BAP). According to Ontario’s *Drug Benefit Formulary/Comparative Drug Index*, the BAP is the lowest amount (calculated per appropriate unit) for which a listed product of a drug can be purchased in Canada for sale in Ontario. The value of any price reduction granted by the manufacturer, wholesaler, or their representatives in the form of rebates, discounts, refunds, free goods, or any other like benefits is then deducted from the BAP. Finally, a percentage – usually 10 percent – is added to arrive at the reimbursement price”). Quite clearly, this OIG study concerning Canadian reimbursement prices did not constitute a public disclosure of VAC’s claims regarding inflated prices for Abbott’s ery products. Truthfully, the use of this report in this context demonstrates the absurdity of having defendants dig for any information whatsoever that even plausibly makes reference to any

similar subject, and then deposit that in front of the court as a “public disclosure of allegations or transactions.”

Abbott continued reference to a 1992 Congressional is equally puzzling. It is clear from the NARD testimony that the hospital prices reported to Congress in 1992 were not available to retail pharmacies, the only group of purchasers relevant to this case. Indeed, retail pharmacists were described as “getting a raw deal” because the lower hospital prices were not available to them. (Response of Relator pp. 8-9). Neither do internal government working papers constitute a public disclosure. *See, e.g., United States ex rel. Ondis v. City of Woonsocket*, 2009 U.S. App. LEXIS 25298 at *11 (1st Cir. 2009) (“public” means outside the government’s bailiwick); *United States ex rel. Putnam v. E. Idaho Reg’l Med. Ctr.*, 2009 U.S. Dist. LEXIS 81416 (D. Idaho 2009); *U.S. ex rel. Feingold v. Adminastar Fed. Inc.*, 324 F.3d 492, 495 (7th Cir. 2003) (in addressing definition of public, “the most germane to [3730(e)(4)] is ‘accessible to or shared by all members of the community’”).

B. Ven-A-Care is an Original Source of its Allegations Concerning the Ery Drugs

VAC has also established that it was an original source of the Ery price information. “To establish original source status knowledge, a *qui tam* plaintiff must allege specific facts – as opposed to mere conclusions – showing exactly how and when he or she obtained direct and independent knowledge of the fraudulent acts alleged in the complaint and support those allegations with competent proof.” *United States ex rel. Hafter v. Spectrum Energy Care, Inc.*, 190 F.3d 1156 at 1162 (10th Cir. 1999). VAC has done precisely that, in detailed testimony explaining its acquisition of Ery price information, clearly independent of any possible prior disclosure. *See* Thomas Decl. Ex. B, Lockwood, 4-23-2009, 22:14-26:16; 11:19-15:16. *See United States ex rel. West v. Ortho-McNeil Pharm., Inc. (In re Pharm. Indus. Average Wholesale Price Litig.)*, 538 F. Supp. 2d 367, 387 (D. Mass. 2008) (knowledge is independent because “as

someone with personal experience, Relator need not rely upon the public disclosure for his knowledge of the alleged bribery scheme”).

Abbott has ignored the testimony and documentation that Ven-A-Care provided its information to the Government about the Abbott Erythromycin drugs and misstates the record. Abbott Reply, pp. 10-11. Once Ven-A-Care uncovered the spreads on the Abbott Erythromycin drugs, it provided the information to the Government along with the McKesson Econolink database that revealed the spreads. *See* Thomas Decl. Ex. C, Lockwood, 4-24-2009, 289:9-290:22; 293:7-18; 295:2-21; and 296: 20-299:17. Even after the initial discussion, Ven-A-Care had ongoing communications with the Government about the spreads on Abbott’s Erythromycin drugs. *Id.* The record of pricing information contained in the Econolink database given to the Government prior to filing the First Amended Complaint, including the Abbott Erythromycin drugs, is included in Ven-A-Care’s Reply, Ex. D., Jones Declaration, paragraph 23, Ex. 7. Prior to filing its complaint with Abbott Erythromycin claims, Ven-A-Care also wrote a letter to the Government stating its intent to add claims for Abbott’s Erythromycin Drugs and providing pricing information which revealed the excessive payments for Abbott’s drugs. Reply, Ex. C. Jones Declaration, Ex. 2, Tab 117.

Abbott also declares that Ven-A-Care had “shuttered its doors to patients” and wasn’t in a position to observe the marketplace. Reply, p. 14. Although Ven-A-Care was not a thriving business in 2000 and 2001, it maintained its pharmacy license and was able to purchase and dispense drugs. *See* Thomas Decl. Ex. D, Jones, December 9, 2008, 1082:11-1083:12; 1145:20-1152:19; Thomas Decl. Ex. E, Lockwood, July 28, 2009 322:5-322:22; Thomas Decl. Ex. B, Lockwood, 4-23-2009, 66:20-70:3. As a licensed pharmacy, Ven-A-Care was a target of the inducements created by Abbott for its Erythromycin drugs and received the prices for the drugs

from McKesson Econolink. Thus, Ven-a-Care had direct and independent knowledge of the allegations of in its Complaint because, as a licensed pharmacy and industry insider, it was in a position to observe the fraud that was occurring.

Accordingly, Abbott's Motion to Dismiss for lack of jurisdiction should be denied.

Date: December 18, 2009

Respectfully submitted

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*For the relator, Ven-A-Care of the Florida
Keys, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2009, I caused a true and correct copy of the foregoing Ven-A-Care of the Florida Keys, Inc.'s Surreply to Abbott Laboratories Reply in Support of Motion to Dismiss for Lack of Subject Jurisdiction Under the False Claims Act to be served via LEXIS File & Serve electronic filing service pursuant to CMO #2 in this case.

/s/ Susan Thomas
Susan Schneider Thomas